Remarks by Ranking Member Frank Pallone, Jr.
House Energy and Commerce Subcommittee on Health
Hearing on "21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communications"

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Thank you Chairman Pitts. Today's hearing is a broader effort to better understand how data collection and the exchange of patient information can be improved to help facilitate 21st Century Cures.

The development process of medical products, as we have learned, has many layers. Throughout our meetings on this initiative we have heard that FDA and NIH are driving medical advances and innovative approaches to clinical trial designs. NIH also develops and funds the basic research that makes medical advances possible. FDA, meanwhile, has made full use of early indicators of effectiveness, when the science justifies their use, to enable it to approve drugs based on more limited data than would otherwise be possible.

But there are still challenges to taking full advantage of these advances. For example, we've heard that there are obstacles to patient recruitment for clinical trials. Today I hope we can better understand about what methods

can be used to facilitate initial product development but also allow for further evaluation of the effects of drugs and devices already on the market. I am particularly interested in the role patient registries and electronic health records can play.

We all want the best cutting edge medicines and treatments to get to the patients who need them. But we must also ensure that we have good tools for post market monitoring. So I'm also interested in how electronic health records can facilitate such monitoring and enable greater participation in clinical trials, while also safeguarding patient privacy under HIPAA.

Another topic we will hear extensively about today is how drugs and devices, once developed, get reimbursed - highlighting the process by which new drugs and devices under federal health programs like Medicare gain coverage. Clinical trials don't always provide the necessary clinical evidence to enable the Medicare program to determine whether the coverage of a particular drug or device is reasonable and necessary for its particular patient subpopulation. With the inability of Medicare to negotiate prices and the increasing price of new drugs and biologics, it is incumbent upon Medicare to be very diligent in its coverage decisions.

Getting a treatment or a cure to a patient has implications for industry, payors and patients alike. So how do we ensure access to these products? In addition, medicines and treatments alone will not ensure the best outcomes. Providers have a critical role to play in the quality of care patients receive.

Mr. Chairman, these are complicated issues. I want our researchers and scientists to have access to the funding necessary to make discoveries; I want our companies to operate in an environment where innovations can flourish; and I want patients to have access to safe and effective treatments. I'm not entirely sure a package of laws is needed to accomplish all of these goals, but I'm hopeful that Democrats and Republicans can work together moving forward to accomplish these goals.

Thank you.